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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,830

10/20/2005

Toshimitsu Nakashima

21581-00476-US

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30678

7590

01/05/2010

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EXAMINER

PROUTY, REBECCA E

ART UNIT

PAPER NUMBER

1652

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,830	Applicant(s) NAKASHIMA ET AL.	
	Examiner Rebecca E. Prouty	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-14 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/8/09 has been entered.

Claims 7, 8, and 15 have been cancelled. Claims 1-6 and 9-14 are still at issue and are present for examination.

Applicants' arguments filed on 12/8/09, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 2 and 9-14 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 1/11/08.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Satoshi et al. (JP 2001/340078) in view of Naylor et al. (WO 96/25509). The rejection is explained in the previous Office Action.

Satoshi et al. describe a process for producing polyester comprising 3HB and 3HH using *Alcaligenes eutrophus* (*Ralstonia eutropha*) using oils or fats as carbon source. Satoshi et al. also describe controlling the molar ratio of 3HH by altering the amount of added oil/fat or fatty acid that is used as a carbon source, the use of coconut oil; palm oil, and palm kernel oil as the oil/fat, a composition of fatty acid comprising 47% lauric acid as a carbon source, the use of microorganisms transformed by a recombination vector that contains the gene of a polyester polymerizing enzyme isolated from *Aeromonas caviae*. Satoshi et

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al. also states that if the oil/fat is added in a large amount at one time, the concentration of dissolved enzyme in the culture liquid may be decreased and because fatty acids are cytotoxic and may inhibit growth. Therefore, a method in which the fatty acid is added in divided amounts such that they do not inhibit growth or a method in which they are added continuously to maintain a concentration that does not inhibit growth is preferred. Satoshi et al. do not teach keeping the a constant specific substrate feed rate (i.e., a constant value of fat or oil added per net weight of cells).

Naylor et al. (WO 96/25509) describe a method of producing a PHA comprising culturing *Alcaligenes eutrophus* in which the carbon source is fed gradually to avoid a toxic concentration of substrate and to maintain a constant oil uptake rate (i.e., 0.13g/g of non-PHA cell mass/hr (see page 7)). Thus Naylor et al. are in fact maintaining a constant specific substrate feed rate of the carbon source. Naylor et al further teach that phosphorus restriction can be used to increase PHA accumulation (see page 4). Naylor et al. teach that their fermentation conditions produce high yields of PHA.

Therefore, it would have been obvious to one of ordinary skill in the art to apply the carbon source feeding strategy of

Naylor of the PHA culture methods of Satoshi et al. in order to increase the yield of PHA.

Applicants argue that it was concluded in the previous office action, that it would have been obvious for a skilled person to apply the carbon source feeding strategy of Naylor et al. to the PHA culture methods of Satoshi et al. in order to increase the yield of PHA but, even based on Naylor et al., it is impossible to expect that the monomer composition of the copolyester can be adjusted as achieved in the present invention. Applicants argue that the purpose of Naylor et al. was to avoid toxicity. Average oil uptake ratio in Naylor et al. has nothing to do with controlling the monomer ratio of the copolyester. However, this is not persuasive as it is not necessary for a finding of obviousness that the modification of the prior art be made for the same reasons as applicants reasons. All that is necessary is that the art provide a reason to make the necessary modification to arrive at the claimed methods not that the reason be identical to that of applicants. The avoidance of toxicity clearly provides a skilled artisan the needed reason to make the necessary modification.

Applicants further argue that as the purpose of adjusting the oil uptake ratio, the method to obtain copolyester, and the composition of the copolyester in Naylor et al. are all

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different from the present invention it would be impossible for persons skilled in the art to expect the effects of the present invention from applying an average oil uptake ratio from Naylor et al. to the PHA production system of Satoshi et al. However, this is not persuasive as it is not necessary for one of skill in the art to expect that a skilled artisan could control the monomer ratio of a copolyester for one of skill in the art to have found the claimed methods obvious as a skilled artisan would have found it obvious to reduce toxicity and therefore increase PHA production by the claimed methods. However, this is not persuasive as each of Satoshi et al. and Naylor et al. disclose methods of producing PHAs using a fatty acid/oil as the carbon source and thus the disclosure of Naylor et al. of reducing the toxicity of higher concentrations of such carbon sources would have clearly been relevant to the methods of Satoshi et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval

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(PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
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